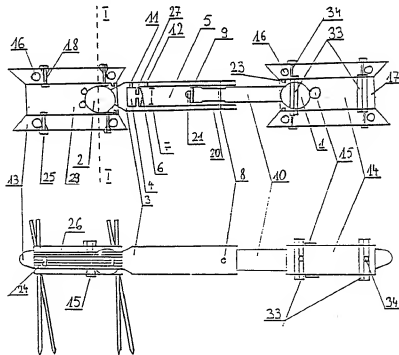




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(21) International Application Number: PCT/US93/08639 (22) International Filing Date: 15 September 1993 (15.09.93) (30) Priority data: P.295943 15 September 1992 (15.09.92) PL (71) Applicant (for all designated States except US): DYNASTAB LIMITED PARTNERSHIP [US/US]; 47 Episcopal Road, Berlin, CT 06037 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): DESZCZYNSKI, Jaroslaw [PL/PL]; ul. Zakrzewska 14A/19, 00-737 Warszawa (PL). KARPINSKI, Janusz [PL/PL]; ul. Bartosika 3 m 15, 03-982 Warszawa (PL). DESZCZYNSKI, Waldemar [PL/PL]; ul. Zakrzewska 14A/19, 00-737 Warszawa (PL).		(74) Agents: RECHTIN, Michael, D. et al.; Reinhart, Boerner, Van Deuren, Norris & Rieselbach, 1000 North Water Street, Suite 2100, Milwaukee, WI 53202 (US). (81) Designated States: AT, AU, BB, BG, BR, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: DYNAMIC COMPENSATING STABILIZER**(57) Abstract**

A dynamic compensating stabilizer for use in treating bone fractures is disclosed. A hydraulic (5) and a pneumatic (4) system is employed for adjusting the length of the stabilizer, allowing for controllable dynamic loading of osteosynthesis and for rehabilitation. A split coupling block (17) changes the inclination of intraosteal screws. A manipulator (30, 31, 32) able to perform functions in all planes is also disclosed.

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DYNAMIC COMPENSATING STABILIZER

The invention refers to a dynamic compensating stabilizer for use in functional therapy of bone fractures.

It enables the reduction of fractures, stabilization of fractured bones after reduction and achievement of correct synostosis.

There are known fractured bone stabilizers for use in cases of periarticular and bone shaft fractures. They constitute usually metal structures consisting of tubes, bars, links and intraosteal screws. Some of them are provided with articulated joints used to restore motorial abilities of damaged or injured human skelton joints to facilitate repositioning of fractured bones. Adjustment of the stabilizer's length is accomplished by turning an adjustment screw in an appropriate direction or by appropriately moving links along a bar. Dynamic behavior of such stabilizers is ensured by suitable springs being so arranged as to cause axial movement after loosening a locking screw. In these known stabilizers, it is difficult to determine correctly required pretensioning of such springs as well as to control correct positioning of stabilizer's axis and articulated joint in respect to axes of fractured bone fragments and a human skeleton joint involved.

In order to ensure required stiffness and strength, such known stabilizers are constructed as frame structures surrounding a limb injured over its whole circumference or a part thereof. This causes such stabilizers to be rather large in size and heavy. Further, these designs make it difficult to get access to wounds associated with a particular injury or postoperative ones. Frequently used introduction of intraosteal screws, not rarely right through a bone in question, may be associated with a serious risk. Furthermore, their use either requires an operative intervention which is burdensome for a patient or reduction of fractures being done externally based on guess work which makes correct repositioning difficult and worsens the results of treatment.

The therapeutic process is based on experience, physical examinations, interviewing a patient and some auxiliary or additional investigations. It is completely impossible to verify correctness of data obtained from interviewing a patient, in particular those referring to intensity of exercises and loading forces. A patient is unable to determine whether actual force loading an injured limb is or is not within the limits recommended by a physician.

A stabilizer according to the present invention avoids these disadvantages of the prior art stabilizers by substituting a hydro/pneumatic system for hitherto

used length and force adjustment mechanical components such as screws and springs. This system makes it possible, by admission or discharge of corresponding amount of hydraulic fluid into or from a hydraulic cylinder chamber, to adjust exactly the length of the stabilizer as desired.

Expansion of gas in a pneumatic chamber with tensile force being applied to the stabilizer results in stretching a membrane and resilient extension of the stabilizer. A partitioning wall with an appropriately sized orifice provided in the hydraulic chamber offers substantial resistance to hydraulic fluid flow and distributes over a substantial period of time any suddenly increasing loads. By means of pressure gauge or pressure transducer connected to the pneumatic chamber or, preferably, to the hydraulic one associated with an appropriate electronic circuit it is made possible to precisely control the loads transmitted to a limb in question. The electronic circuit through appropriate signaling (e.g. audible alarm signals) provides a patient involved with reliable information about the load actually applied to the injured limb such as too high or too little load applied to the limb. A memory enables storage of the total number of loads applied to a limb along with total number of external overloadings which may unfavorably influence the course of treatment.

In order to improve stiffness of the whole stabilizer/limb system provisions have been made for multiplane introduction of intraosteal screws. Adjustment of angles between these screws and longitudinal axis of a bone in question along with increasing or decreasing the stabilizer-to-bone distance is also possible by providing adjustably positioned additional blocks.

In order to improve the precision of fracture reduction and to protect medical personnel against X-rays while performing such reduction, a stabilizer according to the present invention has been provided with a remotely controlled manipulator. This manipulator serves to correct any displacements of fractured bone fragments, while allowing monitoring of the displacements on an X-ray monitor situated at some distance from the X-ray unit or behind a lead shield separating it from that unit.

The manipulator consists of a base and two or three functional units, each of them being provided with five or six individually, remotely or directly, controllable moving members.

A single moving member has a movable part with one degree of freedom and its own hydraulic, electric or pneumatic actuator. The manipulator's gripping devices are coupled to a bone to be manipulated through intraosteal

screws and their associated coupling blocks of the stabilizer. The manipulator's base is attached to a special stand or operating table.

Several preferred embodiments of the invention demonstrating it by way of example are illustrated in the drawings attached wherein:

Fig. 1 shows a schematical top view of the stabilizer in longitudinal section;

Fig. 2 shows a side view of the stabilizer in longitudinal section;

Fig. 3 shows a cross-sectional view of the stabilizer of Fig. 1 along line I-I indicated in that figure;

Fig. 4 shows one of moving members of the stabilizer in longitudinal section along with its associated elastic tank;

Fig. 5 shows a schematical side view of the manipulator; and

Fig. 6 shows a schematical top view of the manipulator.

As shown in Fig. 1, the stabilizer consists of linking member 29 formed by a ball journal 1 and an element 10 with a longitudinal slot 20 formed therein. At the end of element 10, a hydraulic seal 9 (e.g. in the form of O-ring) is mounted. The member 10 is slidably movable inside the member 3 wherein it is stabilized to prevent its rotation by means of pin 8 slidably engaging the slot 19 and mounted in the member 3. The member 3 incorporates a ball journal 2 being a part of a ball-and-socket articulated joint. Inside the member 3, there is a pneumatic chamber 4 provided with a regulating valve 11 and separated by means of flexible membrane 6 from hydraulic chamber 5 which is also provided with a regulating valve 12. The membrane 6 is supported on its side facing the chamber 4 by means of rigid perforated baffle 27. Inside the hydraulic chamber 5 there is a partition wall 7 with an appropriately sized orifice. Admission or discharge of hydraulic fluid through the valve 12 into or from the hydraulic chamber 5 results in lengthening or shortening of the stabilizer respectively. Resistance to flow of hydraulic fluid through the orifice in the partition wall 7 causes efficient vibration damping when the stabilizer is being loaded. As soon as a compressive load has been relieved, gas from the pneumatic chamber 4 expands and flows through perforations or the baffle 27 and enables resilient damping in the direction of stretching. In the pneumatic chamber 4 or, preferably, in the hydraulic one 5, there is a pressure sensing element 21 preferably electrically connected to an electronic storage, signaling and readout circuitry. This enables monitoring of the rehabilitation process. This circuitry can be placed within the coupling block 17 or in a separate enclosure. The

coupling block 17 consists of a central part 1, preferably in the form of tube, carrying at its end a clamping ring 23 of internal diameter smaller than the outer diameter of the ball journal 1 and locked in place by means of taper screws 15. On side faces of the central part 14 there are recesses, preferably in the form of elongated grooves 26, intermeshing with corresponding protrusions on contiguous surfaces of the part 13.

Appropriate screws with nuts 25 passing through mutually aligned holes 24 in the parts 13 and 14 serve to join the last mentioned parts together. After tightening the nuts on these screws, the parts 13 and 14 are interlocked in respect to each other along with locking in place the intraosteal screws 16. This enables adjustment of the angle at which the screws 16 are inclined in respect to each other. In the embodiment shown in Fig. 4, an elastic tank 28 is used in place of the hydraulic chamber 5. This chamber takes there the form of elastic tank 28 also provided with a regulating valve. This eliminates the necessity to use the hydraulic seal.

The pneumatic chamber 4 with its associated regulating valve 11 and perforated baffle 27 of the previously described embodiment has been retained there. A pressure sensing element can be placed either inside or outside the tank 28. In cases where the members 3 and 10 are circular in their cross sections, it is necessary to prevent their rotational movement around their longitudinal axis while simultaneously allowing their linear movement in axial direction. This is achieved by providing the member 10 with a longitudinal slot 2. A pin 8 having its one end or both ends mounted in the member 3 engages into the slot 2. The pin 8 can comprise either a conventional pin or can take the form of a screw or bolt with a nut.

Figs. 5 and 6 illustrate a manipulator designed to operate in association with a stabilizer according to the present invention. The manipulator comprises a base 30 (to be attached either to a special stand or operating table) and two or three functional units 31, depending on what kind of fracture is to be treated - a periarticular or bone shaft fracture. Each functional unit 31 consists of five or six members, each of them having a mount for attaching the next one and an actuator, preferably in the form of a hydraulic cylinder 32. Instead of a hydraulic actuator, an electric or pneumatic one can be used. Each of these members is able to be moved by its associated actuator in a single direction only and can be individually controlled either locally or remotely. The actuators are provided with pressure or force sensing elements. It is advantageous to simulate

the forces produced in the manipulator in its control levers. Rotational and angular displacements are effected by the members performing curvilinear motion. Forces produced by the manipulator are transmitted to a bone involved through the coupling blocks and intraosteal screws of a stabilizer.

Adjustment of the angle at which the intraosteal screws are inclined in respect to each other is effected by rotating the rings 33 (together with their associated members 13) around the longitudinal axis of the central member 14 and locking them in place by means of screws 34 screwed into corresponding tapped holes in the ring 33.

What Is Claimed Is:

1. A dynamic compensating stabilizer comprising links, coupling blocks, articulated joints and intraosteal screws characterized in that the link 29 consists of a member 10 provided with a ball journal 1 in its central portion and having a slot 20 with a pin 8 engaging it and carrying a seal 9 at its end, the member 10 being slidably mounted inside another one 3 provided with a ball journal 2, pneumatic chamber 4 with its associated valve 11, membrane 6, perforated baffle 27 hydraulic chamber 5 with its associated valve 12, partition wall 7, pressure sensing element 21 being preferably electrically connected to an electronic storage, signalling and readout circuitry; wherein the ball journals 1 and 2 are seated in their respective sockets of coupling blocks 17 and 19 or the ball journal 1 is seated in a socket of the coupling block 17 whereas the ball journal 2 is seated in a socket of an "active articulated joint" of similar design, located above a joint being treated.

2. A dynamic compensating stabilizer as per Claim 1, characterized in that the coupling block 17 consists of a central member 14 in which the ball journal 1 lockable in place by means of taper screws 15 and clamping ring 23 is seated; the coupling block 17 being provided on its side faces with holes 24 for screws 18 with tapered nuts 25 and having recesses, preferably, in the form of elongated grooves 26, engaging corresponding protrusions between similar grooves in surface of two members 13, preferably plastic ones, having holes for intraosteal screws 16.

3. A dynamic compensating stabilizer as per Claim 1, characterized in that the hydraulic chamber is formed by an elastic tank 28, preferably made of rubber, with its associated regulating valve, the tank being associated with either of the two members 10 or 3.

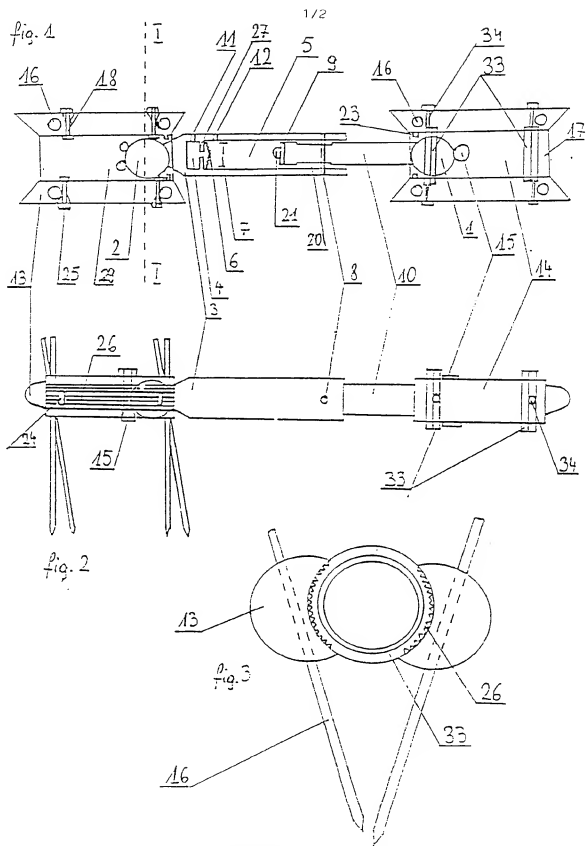
4. A dynamic compensating stabilizer as per Claim 1, characterized in that the members 3 and 10 are of circular cross section and in such cases are provided with an axially running slot 20 on one of them and a pin 8 or screw or bolt with nut engaging that slot on the another one of these two members 3 or 10 to prevent their rotation in respect to each other or they are of non-circular mutually complementary cross-sectional shape which by itself prevents their relative rotational movement.

5. A manipulator for reduction of fractures, characterized in that it does away any displacement of fractured bone fragments in respect to each other by appropriately moving its slidable or rotatably movable members on their

their common base, such having a mounting base and its own fluidic 32 or electric actuator; the members being brought together to form two or three functional units 31 each consisting of five or six such members, each of them being individually, either remotely or locally, controllable, preferably with the aid of a processor and preferably using a feedback mode of control and having their gripping devices coupled to intraosteal screws and coupling block of the stabilizer on one side and with the manipulator's base 30 on the other.

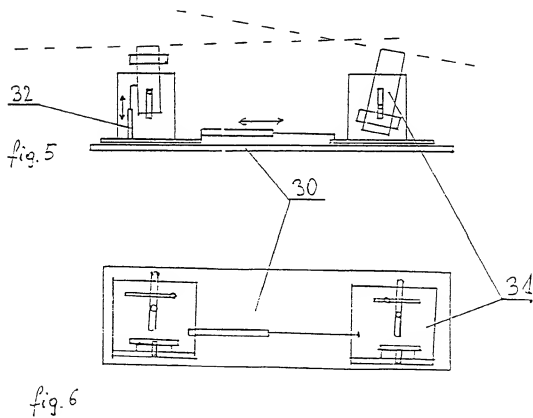
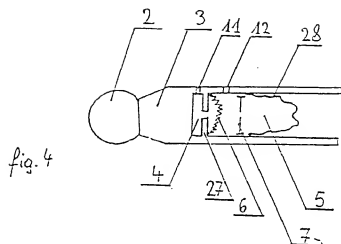
6. A manipulator as per Claim 5, characterized in that rotational and angular displacements of fractured bone fragments are accomplished by manipulator's members performing curvilinear motion.

7. A dynamic compensating stabilizer as per Claim 2, characterized in that adjustment of inclination angles of stabilizer's intraosteal screws is being done by rotating the rings 33 together with their associated members 13 around the longitudinal axis of the central member 14, the rings being locked in place by means of screws 34 screwable into tapped holes provided in the ring 33.



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INTERNATIONAL SEARCH REPORT

 national application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61B 17/60

US CL : 606/57

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/58, 59, 55, 54, 61, 104, 105

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

search terms: hydraulic and pneumataic

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,502,473 (Harris et al.) 05 March 1985, see figure 7.	5 and 6
A	US, A, 5,026,372 (Sturtzkopf et al.) 25 June 1991, see column 4, lines 64-68.	1 and 4

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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